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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,675	07/03/2003	John H. Erickson	03-006 US	7289

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EXAMINER	
SMITH, TERRI L	
ART UNIT	**PAPER NUMBER**
3762	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/613,675	ERICKSON, JOHN H.	
	Examiner	Art Unit	
	Terri L. Smith	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5,7,9-19 and 22-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5,7,9-19 and 22-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 July 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed on 14 July 2006 with respect to claims 2, 10–19 and 22–28 have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment.

2. Additionally, Applicant's arguments filed on 14 July 2006 have been fully considered but they are not persuasive. Regarding Applicant's arguments that "...the endocardial lead system of Flynn is a fundamentally different type of device and is adapted for a fundamentally different purpose, and thus, Flynn does not teach or suggest the subject matter recited in claims 1, 7, 10, 17, 18, 22, and 24," Examiner respectfully disagrees. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). Further, Flynn et al., U.S. Patent 6,141,594 teaches, "although the use of the lead has been described for use in a cardiac pacing system, the lead could also be applied to other types of body stimulating systems" (column 9, lines 53–55). Consequently, the invention of Flynn et al. is capable of being used for spinal cord stimulation.

3. All of the dependent claims remain rejected due to their dependency from the rejected independent claims in view of Examiner's arguments above. Additionally, Examiner maintains the rejection under 35 U.S.C. 102(b) as anticipated by Flynn et al., U.S. Patent 6,141,594 for claims 1, 5, 7, 9 as submitted in the Office Action mailed on 14 April 2006 and as re-submitted herein below.

Claim Objections

4. Applicant is advised that should claim 12 be found allowable, claim 15 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 2, 5, 7, 9–19 and 22–28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claimed subject matter "to allow fibrosis around the first and second lead bodies to occur" in combination with the other elements in the claims. The original specification did not disclose any teaching on allowing fibrosis around the first and second lead bodies to occur.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the Applicant regards as his invention.

8. Claims 1, 2, 5, 7, 9–19 and 22–28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

Applicant regards as the invention. The term "sufficient" in claims 1, 7, 10, 17, 18, 22 and 24 is a relative term, which renders the claim indefinite. The term "sufficient" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The recitation that an element (in the instant case, "a period of time") to perform a given function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense.

Claim Rejections - 35 USC § 102

Claim Rejections - 35 USC § 103

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the Applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the Applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1, 5, 7, 9 are rejected under 35 U.S.C. 102(b) as anticipated by Flynn et al., U.S. Patent 6,141,594 or, in the alternative, under 35 U.S.C. 103(a) as obvious over Flynn et al., U.S. Patent 6,141,594.

12. Flynn et al. disclose a lead system (e.g., Figs. 1A–1B and 9, elements 100, 200, 402, respectively), a first lead body having at least one electrode/(first lead) (e.g., elements130/152); a second lead body having at least one electrode/(second lead) (e.g., elements 132/154); a connection member coupled to a first lead body and a second lead body and operable when a connecting member (e.g., element141) is in a first state to maintain at least a portion of a first lead body in a first position relative to at least a portion of a second lead body/(means coupled to a first lead and a second lead for maintaining at least a portion of a first lead in a first position relative to at least a portion of a second lead) (e.g., Figs. 1A–1B); wherein a connection member is resorbed over a sufficient period of time (e.g., column 10, lines 27–29) and when implanted within an epidural space of a patient to allow fibrosis around first and second lead bodies to occur is a functional use recitation and it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). Consequently, the invention of Flynn et al. is capable of being implanted in an epidural space to allow fibrosis around first and second lead bodies to occur because it is similar in size and shape to Applicant's claimed invention, it is used in the heart which requires a small sized lead, and the size of the epidural space has not been defined nor claimed, and the fibrosis has not been claimed. (See alternative 103(a) rejection below)

13. In the alternative, claims 1 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flynn et al., U.S. Patent 6,141,594.

14. Flynn et al. disclose the essential features of the claimed invention and that the lead can be used in other areas of the body as described above but not explicitly a lead implanted within the epidural space of a patient. However, it is well known in the art to have a lead capable of being implanted within the epidural space of a patient because it is well known to make a lead as small as possible to be placed unobtrusively in the body to perform appropriate therapy in the spinal region to treat different problems of the patient, such as pain. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Flynn et al. to include a lead implanted within the epidural space of a patient so that appropriate therapy can be performed for spinal cord needs.

15. Claims 2, 10–19 and 22–25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flynn et al., and in view of Westlund et al., U.S. Patent 5,951,597.

16. Flynn et al. disclose a first lead; a second lead; and a connection member, comprising: a first portion attached to a first lead, a second portion attached to a second lead and coupled to a first portion as described in paragraph 12 above; a third portion coupled to a first and second portion (e.g., Figs. 4A–4B, elements 152-first portion, 154-second portion, and 166-third portion) [Examiner notes that this continuous dissolvable medical adhesive is consistent with Applicant's disclosure that the portions 104, 106, 108 may also be made into one unitary portion, and the dissection into three portions is for illustrative purposes only (e.g., page 12, lines 14–20)]. Flynn et al. do not disclose resorbable polymer material that is resorbed when implanted

within a patient over a sufficient period of time to allow fibrosis to occur. However, Westlund et al. disclose resorbable polymer material that is resorbed when implanted within a patient over a sufficient period of time to allow fibrosis to occur (e.g., column 3, lines 37–45 and 47–49) to allow for efficient and comfortable implantation of a device and to safely allow subsequent reliable placement of the device at a desired site notwithstanding body movement. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Flynn et al. to include resorbable polymer material that is resorbed when implanted within a patient over a sufficient period of time to allow fibrosis to occur, as taught by Westlund, et al. to allow for efficient and comfortable implantation of a device and to safely allow subsequent reliable placement of the device at a desired site notwithstanding body movement.

17. Alternatively, claims 2, 10, 12, 15, 17, 18, 22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flynn et al., U.S. Patent 6,141,594.

18. Flynn et al. disclose the claimed invention but does not disclose expressly resorbable polymer material. It would have been an obvious matter of engineering design choice to one of ordinary skill in the art at the time the invention was made to modify the resorbable material as taught by Flynn et al., to have resorbable polymer material, because Applicant has not disclosed that resorbable polymer material provides an advantage. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the resorbable material as taught by Flynn et al., because the resorbable material holds the device in a desired position at a designated time and then releases it at the appropriate time to accomplish

and administer therapy. Therefore, it would have been an obvious matter of engineering design choice to modify the resorbable material to obtain the invention as specified in the claim. Additionally, it is well known in the art to use resorbable polymer material to provide a safe surface for implantation and subsequent reliable placement of a device at a desired site notwithstanding body movement.

19. Claims 26–28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flynn et al. and Westlund et al. as applied to claim 24 above, and further in view of Cooke et al., U.S. Patent 5,643,328.

20. Flynn et al. and Westlund et al. disclose the essential features of the claimed invention as described above except for a source comprises a wireless receiver (claim 26), an implantable pulse generator (claim 27), and a controller operable for communicating with a source and controlling a source (claim 28). However, Cooke et al. disclose a source comprises a wireless receiver (e.g., Fig. 3; column 4, lines 47–51) and an implantable pulse generator (e.g., Fig. 1), and a controller operable for communicating with a source and controlling a source (e.g., Fig. 3) to provide an effective implantable cardiac stimulation system with a reliable patient communication apparatus. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Flynn et al. and Westlund et al. to include a source comprises a wireless receiver, an implantable pulse generator, and a controller operable for communicating with a source and controlling a source, as taught by Cooke et al. to provide an effective implantable cardiac stimulation system with a reliable patient communication apparatus.

Conclusion

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this Final Action.

22. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is (571) 272-7146. The Examiner can normally be reached on 7:30 a.m. - 4:30 p.m..

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TLS
March 30, 2007
30 March 2007

GEORGE R. EVANISKO
PRIMARY EXAMINER
4/1/7